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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 405235; **FILE SYMBOL No.**: 88685-G; **PRODUCT NAME**: Glufosinate-Ammonium Technical; **DECISION No.**: 468534; **PC Code(s)**: 128850; **ACTION CODE**: R310; **FOOD Use**: Yes

DATE: February 7, 2013

SUBJECT: Product Chemistry Review of "Glufosinate-Ammonium Technical" TGAI/MUP

FROM: Shyam Mathur
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02-27-13

TO: Kathryn Montague, RM 23
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DP BARCODE: 405235
DECISION No.: 468534
REGISTRATION NO./FILE SYMBOL NO.: 88685-G
PRODUCT NAME: Glufosinate-Ammonium Technical
PC CODE: 128850
REGISTRANT: Orion GFS, LLC
USE: Herbicide
FOOD USE: Yes [X] No [ ]
MRID Numbers: 489039-01 to 489039-06

INTRODUCTION:

The registrant Orion GFS has submitted an application for the registration of the Glufosinate-Ammonium technical grade active ingredient. The technical glufosinate-ammonium is produced by [redacted] which is represented in the proposed basic CSF (dated 07-10-2012). In support of the basic CSF, the registrant has submitted group A & group B product chemistry data with 489039-01 to 489039-06. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 88685-1. TRB has been asked to evaluate and determine the acceptability of the proposed basic CSF (dated 07-10-2012) and the supporting product chemistry data and as well as determine substantial similarity to the cited product.

SUMMARY OF FINDINGS:

1. The findings for Group A guideline data were as follows:

830.1550 (product identity & composition): The registrant submitted a basic CSF (dated 07-10-2012). The product chemistry data corresponding to this guideline submitted on the CSF and in MRID 489039-01 satisfy the data requirements of 40CFR§158.320. The nominal concentration 96.3% for AI concurs with the proposed product label claim nominal concentration 96.3%.

830.1600 (description of materials used to produce the product): The product chemistry data submitted corresponding to this guideline satisfy the data requirements of 40CFR§ 158.325 [MRID No. 489039-01].

830.1620 (description of production process): The registrant provided detailed information on the [redacted] production process for technical/mup. The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.332[MRID No. 489039-01].

830.1670 (discussion on the formation of impurities): The registrant has provided information on the formation impurities and the mechanism of the formation the impurities. Only [redacted] impurity was identified during the analysis. The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.340[MRID No. 489039-01].

830.1700 (preliminary analysis): The product chemistry data submitted corresponding to this guideline to support the claims on the CSF and satisfy the data requirements of 40CFR§158.345[MRID No. 489039-02 to -04]. Impurities are identified and the upper limits stated on the CSF for each are supported by the five-batch analysis.

830.1750 (certified limits): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.350 [MRID No. 489039-01]. The registrant has proposed standard certified limits for the active ingredient whereas the proposed certified limits for the impurities are based on the five batch analysis.

830.1800 (enforcement analytical method): The product chemistry data submitted corresponding to this guideline satisfy the data requirements of 40CFR§158.355. The active ingredient content was determined by HPLC-UV using external standard method. The analytical method was validated for precision, linearity, and accuracy [MRID No. 489039-02 to 489039-04].

2. The product chemistry data submitted corresponding 830 series group B guideline (physical-chemical properties) satisfy the data requirements of 40CFR§158.310(e).

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for glufosinate-ammonium Technical (produced by [redacted]) to support the proposed basic CSF and has concluded that:

1. The product chemistry data submitted for guideline 830 Series group A are acceptable.

2. The proposed basic CSF (dated 07-10-2012) is acceptable. The registrant has listed [redacted] new impurity in the proposed basic CSF (dated 07-10-2012) which is not present in the cited product [Reg. No. 88685-1; basic CSF (dated 9-10-2011)]. According to Dr. Byron Backus (toxicologist TRB), the presence of this additional impurity will not cause any adverse health & environment effects based on its chemical structure. This impurity is considered as not of toxicological concern.

3. The group B product chemistry data submitted for the proposed product are acceptable.

4. The proposed product with File Symbol No. 88685-G was determined to be substantially similar to cited product with Reg. No. 88685-1 from product chemistry point of view. The proposed product contains [redacted] new impurity of non-tox concern which is not present in the cited product. Also there is significant difference in the pH values of the proposed and cited product (7.0 in proposed vs 3.75 in cited). However, this conclusion is contingent upon the acute tox studies determinations.

830.1550. Product identity & composition: (MRID No. 489039-02)

Common Name: Glufosinate-ammonium

Chemical name (CAS): Ammonium (±)-2-amino-4-(hydroxymethylphosphinyl) butanoate

(IUPAC): Ammonium DL-homoalanin-4-yl(methyl)phosphinate

CAS No.: 77182-82-2

PC Code No.: 128850

Empirical Formula: $C_5H_{15}N_2O_4P$

Molecular Weight: 198.2 g/mol

Structural Formula:

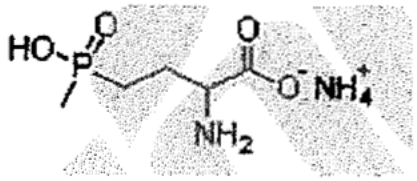

Table 1. Manufacturing and Impurity Data for Propiconazole Technical TGAI

GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	489039-01	A	Registrant has submitted a CSF basic formulation dated 07-10-12 with nominal concentration of 96.3% for AI. The nominal concentration agrees with the label claim nominal concentration.
830.1600	Description of materials used to produce the product	489039-01	A	Suppliers are identified and MSDSs are provided for all the inert ingredients used to produce the product.
830.1620	Description of production process	489039-01	A	[redacted] batch production process has been described in details. All the significant parameters for each step of the manufacturing process have been provided.
830.1670	Discussion of formation of impurities	489039-01	A	Impurities discussed and identified. Registrant has identified only [redacted] impurity (of non-toxicological concern) and has provided mechanism of its formation. The impurity has been identified during the five batch analysis.
830.1700	Preliminary analysis	489039-02 To 489039-04	A	The five batch analysis of the glufosinate-ammonium technical was conducted to determine the contents of the active ingredient and the impurities. The HPLC-DAD detector with external standard technique was used for the determination of the active ingredient and the impurities. The identity of the active ingredient was further confirmed by NMR and MS techniques. The analytical methods were validated for linearity, accuracy, precision , LOQ and LOD.
830.1750	Certified limits	489039-01	A	CSF standard limits for AI. Proposed limits for the impurities are based on five batch analysis.
830.1800	Enforcement analytical method	489039-02	A	HPLC-DAD method with external standard technique.

A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);

Manufacturing process information may be entitled to confidential treatment

830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of Glufosinate-Ammonium Technical TGAI

GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	489039-05	A	White
830.6303	Physical state	489039-05	A	Crystalline powder
830.6304	Odor	489039-05	A	Slightly pungent
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	489039-06	A	Stable at normal and elevated (54 °C) conditions for 14 days as determined also with Fe and Al metals
830.6314	Oxidation/reduction: chemical incompatibility		NA	
830.6315	Flammability		NA	
830.6316	Explodability		NA	
830.6317	Storage stability		NA	
830.6319	Miscibility		NA	
830.6320	Corrosion characteristics			
830.7000	pH	489039-05	A	6.13 @ at room temperature
830.7050	UV/Visible absorption		NA	
830.7100	Viscosity		NA	
830.7200	Melting point	489039-05	A	210.1°C
830.7220	Boiling point		NA	
830.7300	Density	489039-05	A	1.37 g/mL @ 20 °C
830.7370	Dissociation constants in water (DC)	489039-05	A	pKa = 9. 12 @ room temperature
830.7550	Partition coefficient	489039-05	A	log $P_{o/w}$ = -4.03 @ 25 °C
830.7840	Water solubility	489039-05	A	Distilled water = 1375 g/L n-Hexane = <1g/L Ethyl acetate = < 1 g/L Acetone = <1 g/L
830.7950	Vapor pressure	489039-05	A	2.93 x 10^{-5} Pa @25 °C

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ;
U = Up-grade (additional information required); W = waivers

830.1800 (enforcement analytical method) (MRID No. 489039-04)

The contant of the glufosinate-ammonium technical was done on HPLC-DAD fitted with a Eclipse XDB-C_8 column (150 x 4.6 mm, 5 µm). The content of propiconazole was measured by HPLC-UV (detector operating 230 nm) with external standard quantitative method. The method was validated for linearity, range of linearity, precision and accuracy.

Details of the method can be seen in the MRID given above.

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CONFIDENTIAL APPENDIX

[redacted]

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[redacted]

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CONFIDENTIAL APPENDIX